(4)

No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

BARR LABORATORIES, INC., APOTEX, INC., BERNARD C. SHERMAN, GENEVA PHARMACEUTICALS, INC., AND INTERPHARM, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF *AMICI CURIAE* IN SUPPORT OF PETITIONER

Of counsel:
Stephan E. Lawton
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1625 K Street, NW
Washington, DC 20006
(202) 857-0244

Matthew B. Van Hook
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA
1100 15th Street, NW
Washington, D.C. 20005
(202) 835-3400

Jeffrey P. Kushan,
Counsel of Record
David L. Fitzgerald
Marinn F. Carlson
POWELL, GOLDSTEIN, FRAZER & MURPHY LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

29 pp

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Pursuant to Rule 37.2(b) of the Rules of this Court, the Biotechnology Industry Organization ("BIO") and Pharmaceutical Research and Manufacturers of America ("PhRMA") move for leave to file the accompanying brief as *amici curiae* in support of the petition for a writ of *certiorari*. Petitioner Eli Lilly & Co. ("Lilly") has consented to the filing of the brief *amici curiae*; Respondents Barr Laboratories, Inc. *et al.* have withheld consent.

BIO is the principal trade association representing the biotechnology industry in the United States and abroad. Its more than 1,000 members, including nonprofit institutions as well as commercial entities, engage in research, development and commercialization of new technology in the fields of pharmaceuticals, healthcare, food, and agriculture. The biotechnology industry—as well as the revolutionary advances it has provided in the last twenty-five years—would not exist in the absence of a robust patent system. In many instances, the capital needed to establish and grow biotechnology companies has been secured principally by the promise of enforceable patent rights, particularly for those enterprises founded to bring the benefits of federally-funded research to the public through commercial development. BIO is concerned that the decision of the Federal Circuit in this case will severely compromise its members' ability to secure patents that fully and fairly reflect the value of their inventions.

PhRMA is a trade association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. These companies produce the majority of new pharmaceuticals that are developed and

marketed throughout the world. PhRMA's member companies will invest more than $30 billion this year in discovering and developing new medicines, leading the way in the search for cures. PhRMA estimates that each new drug requires about twelve to fifteen years from pre-clinical and clinical testing through FDA approval. This lengthy development period already cuts significantly into the term of patent protection that is supposed to provide manufacturers their best opportunity to recover the enormous development costs of new drug development. The new rule fashioned by the Federal Circuit in this case threatens to curtail that recovery even further by prematurely terminating patent rights for important inventions.

Neither BIO nor PhRMA has a stake in the final outcome of this patent litigation. However, their members, individually and collectively, have an enormous interest in the proper development of the law governing nonstatutory double patenting. Because of the manner in which research, development, and innovation is conducted in the biotechnology and pharmaceutical sectors, BIO and PhRMA anticipate that the fact pattern giving rise to the double patenting issues in this litigation will be encountered frequently. The double patenting rule articulated in the decision below will, in their view, have a disproportionate impact on the industries they represent.

Lilly's petition for a writ of *certiorari* frames the legal issues implicated by the Federal Circuit decision in terms of the particular facts of its case. However, the decision will have important consequences for the business plans and intellectual property strategies of a wide range of research-based companies, including many members of BIO and PhRMA, as double patenting issues arise before the U.S. Patent and Trademark Office. These organizations therefore wish to provide this Court, as *amici curiae*, their perspective

on the wider implications of the Court's review of the decision below.

The decision of the Federal Circuit includes important doctrinal pronouncements that, if not addressed and corrected in this Court's exercise of its supervisory powers, will have serious negative consequences for the procurement of patents for important therapeutic and other inventions. BIO and PhRMA believe that should the decision stand, it will diminish the patent system's incentives for innovation—the foundation of the biotechnology and pharmaceutical industries.

In keeping with Supreme Court Rule 37.1, the proposed brief *amici curiae* draws the Court's attention to important legal issues of double patenting that are encompassed by, but not discussed at length in, the petition for a writ of *certiorari*. BIO and PhRMA believe that the more thorough development of these issues will be of material assistance to the Court in evaluating the petition.

For the reasons set forth above, BIO and PhRMA request that this Court grant the present motion for leave to file the enclosed brief as *amici curiae*.

Respectfully submitted,

Of counsel:
Stephan E. Lawton
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Matthew B. Van Hook
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA

Jeffrey P. Kushan,
Counsel of Record
David L. Fitzgerald
Marinn F. Carlson
POWELL, GOLDSTEIN, FRAZER & MURPHY LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

December 13, 2001

TABLE OF CONTENTS

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* i

TABLE OF AUTHORITIES vi

BRIEF *AMICI CURIAE* 1

INTERESTS OF THE *AMICI CURIAE* 1

SUMMARY OF THE ARGUMENT 2

ARGUMENT 3

I. The Law of Double Patenting 6

A. Evolution of the Law of Double Patenting 6

B. Terminal Disclaimers Equitably Resolve Double Patenting Problems 9

C. The Two-Way Test Allows Independent Patents for Basic and Improvement Inventions, Regardless of the Order in Which the Patents Issue 10

D. The Two-Way Test Is Applied Infrequently, But It Is Critically Important When It Is Invoked. 12

II. *Certiorari* Should Be Granted Because *Lilly* Conflicts with Federal Circuit Precedent Without Overruling It, Leading to Confusion in the Law 13

III. *Certiorari* Should Be Granted Because *Lilly* Significantly Affects Important Questions of Patent Policy, Threatening Great Harm to Technological Innovation 16

A. The *Lilly* Rule Will Discourage Innovation 16

B. Rapidly Developing Fields of Technology Are Particularly Vulnerable 18

C. Patent Applicants Should Not Automatically Forfeit Rights for Any and All Prosecution Delays 19

D. Action By This Court Is Necessary To Restore a Proper Balance in the Law.....20

CONCLUSION 20

TABLE OF AUTHORITIES

CASES

Eli Lilly and Co. v. Barr Laboratories, Inc. et al., 251 F.3d 955 (Fed. Cir. 2001) ..... passim

Graham v. John Deere Co., 383 U.S. 1 (1966) 8

In re Baird, 16 F.3d 380 (Fed. Cir. 1994) 10

In re Bell, 991 F.2d 781 (Fed. Cir. 1993) 10

In re Berg, 140 F.3d 1428 (Fed. Cir. 1998) ..... passim

In re Braat, 937 F.2d 589 (Fed. Cir. 1991) 11, 14, 15

In re Emert, 124 F.3d 1458 (Fed. Cir. 1997) 14, 15

In re Goodman, 11 F.3d 1046 (Fed. Cir. 1993) .. 8, 11, 14, 15

In re Slayter, 276 F.2d 408 (C.C.P.A. 1960) 11

In re van Ornum, 686 F.2d 937 (Fed. Cir. 1982) 9, 17

In re Vogel, 422 F.2d 438 (C.C.P.A. 1970) 8, 10

In re Zickendraht, 319 F.2d 225 (C.C.P.A. 1963) 9

Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894) 2, 7, 13, 19

Odiorne v. Amesbury Nail Factory, 18 F. Cas. 578 (C.C. D. Mass. 1819) 6

Suffolk Co. v. Hayden, 70 U.S. (3 Wall.) 315 (1865) 7

STATUTES & REGULATIONS

35 U.S.C. § 101 ..... 6, 8

35 U.S.C. § 102 ..... 8, 11, 12

35 U.S.C. § 103 ..... 8, 10, 12

35 U.S.C. § 122 18

35 U.S.C. § 154 ..... 9, 17

35 U.S.C. § 253 ..... 9, 19

37 C.F.R. § 1.321(c)(3) 9, 17

American Inventors Protection Act of 1999, Pub. L. 106-113, 113 Stat. 1536 17

Patent Act, ch. 950, 66 Stat. 809 (1952) 9

RULES

Supreme Court Rule 37.1 iii

Supreme Court Rule 37.2(b) ..... i, 1

Supreme Court Rule 37.6 1

BRIEF *AMICI CURIAE*

Under cover of the accompanying motion pursuant to Rule 37.2(b) of the Rules of this Court, the Biotechnology Industry Organization ("BIO") and Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully submit this brief *amici curiae* in support of the grant of a writ of *certiorari*.[1]

INTERESTS OF THE *AMICI CURIAE*

BIO is a trade association consisting of more than 1,000 companies, academic institutions, and biotechnology centers. BIO members file thousands of patent applications each year for inventions ranging from fundamental technological breakthroughs to important commercial refinements of existing technology.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, and serves as the industry's principal policy advocate. Relying heavily on patent protection to develop and commercialize new therapies, PhRMA members account for more than 75% of brand name drug sales in the United States.

Members of BIO and PhRMA depend on the incentives of the patent system. *Amici* are thus concerned that the law of double patenting be applied consistently and fairly, and in accord with the policy objectives of the patent system.

---

[1] Pursuant to Rule 37.6, *amici curiae* state that no person or entity other than BIO, PhRMA, or their counsel has made any monetary contribution to the preparation or submission of this brief. Petitioner Eli Lilly and Co., though a member of both BIO and PhRMA, did not participate in discussions related to the filing of this brief and, apart from paying regular membership dues, did not contribute to the cost of its preparation. No counsel for Petitioner or Respondents authored this brief in whole or in part.

SUMMARY OF THE ARGUMENT

The decision of the Federal Circuit in this case will lead to severe and undesirable changes to practice before the Patent and Trademark Office ("PTO"). It forces consideration of "double patenting" questions in situations not warranted by precedent, and it invents a new rule that will drastically restrict access to the "two-way" test for nonstatutory double patenting, discussed *infra*. The analysis applied by the court below threatens to diminish the effectiveness of the patent incentives that are critical for the biotechnology and pharmaceutical industries.

This Court has recognized that "an inventor may make a new improvement on his own invention of a patentable character." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 199 (1894). Independent patents for merely "obvious" variations of a first patented invention, however, are prohibited on the theory that granting the second patent would improperly prolong the period of exclusivity beyond the term fixed by statute. Rules against such "double patenting," developed through patent jurisprudence, prevent the *improper* extension of patent rights.

Difficult double patenting questions arise when the grant of a patent on a basic invention is delayed in the PTO until after the grant of a separate patent on a later-filed application for an improvement on the basic invention. In this situation, the PTO must determine whether the separate inventions claimed in the patents deserve independent or linked patent terms. If the PTO concludes the applicant is not entitled to a distinct term for each invention, it may require the applicant to truncate the term of the later-issuing patent.

In these reverse-order situations—where the PTO has already concluded that the later issuing patent claims would not be separately patentable over the earlier patent, absent extenuating circumstances—past precedent of the Federal

Circuit instructed the PTO to consider the patent applicant's behavior as a whole in determining whether the term of the later-issuing patent should be cut short. If the patent applicant is not principally responsible for controlling the rate of prosecution of the two patents (*i.e.*, for creating the "reverse-order" situation), the PTO will instead use what is termed the "two-way" test for patentability, which ordinarily will result in a decision to grant full, unlinked terms for both inventions.

In the decision below, the Federal Circuit has transformed this evaluation into a *de facto* ban on use of the two-way test. It would deny access to the two-way test upon any finding of a single instance of "delay" attributable to the applicant. The decision below conflicts with—but does not purport to overrule—Federal Circuit precedent that looks to the record *as a whole* to assess the applicant's conduct. Its rule will fall most heavily on patent applicants in new technologies, imposing requirements that will be difficult for even the most diligent to meet. As a result, many innovators will be forced to forego the full measure of protection for each of their separately patentable inventions.

Patent policy, as well as the need for clarity and consistency in this commercially vital area of the law, are concerns of national importance. This Court's exercise of its supervisory power is therefore warranted.

ARGUMENT

In the decision below, the Court of Appeals for the Federal Circuit articulated a new rule for evaluating nonstatutory double patenting. This new rule represents a significant departure from established law, implicating important questions of patent policy, and thus calls for the exercise of this Court's supervisory power. The reasoning adopted by the Federal Circuit will directly and inevitably affect the practices of innovators in patenting new and useful improvements on patented technology. Federal

Circuit law is binding for all patent litigation in the district courts and for all proceedings before the PTO. The effect of the decision below is therefore far-reaching and, *amici curiae* believe, raises questions of national importance.

The questions presented to the Court involve nonstatutory double patenting—whether a patentee has improperly extended the grant of exclusivity by separately patenting a second, related invention. The rules in this area of the law reflect basic policy decisions—made by the courts—about when an inventor should or should not be entitled to separate and distinct patents for each of two inventions. These rules are of enormous importance to innovation-driven enterprises with extensive research programs, such as the members of BIO and PhRMA. However, the new rule announced below virtually precludes the possibility of the PTO issuing independent patents to a single entity for both an original, "basic" invention and a later, *fully patentable* "improvement" invention under certain circumstances. Because it threatens to deter the early disclosure of original inventions, this decision bears close scrutiny.

The Court of Appeals for the Federal Circuit twice held a claim of U.S. Patent No. 4,626,549 ("the '549 patent), owned by Eli Lilly and Co. ("Lilly"), invalid on grounds of nonstatutory double patenting. *See Eli Lilly and Co. v. Barr Laboratories, Inc. et al.*, 251 F.3d 955 (Fed. Cir. 2001), Pet. App. at 1a, *vacating en banc* 222 F.3d 973 (Fed. Cir. 2000), Pet. App. at 57a. In its second panel decision, based on different grounds than the first, the court held that the claim of Lilly's earlier-filed but later-issuing basic invention patent was invalid in view of a claim that had been granted for a *later-filed but earlier-issued* improvement invention. The basic legal issue—double patenting involving claims that issue in "reverse order"—has been addressed in several Federal Circuit decisions. In this case, however, the court departed from its established precedent to fashion a new,

mechanical rule, under which *any* "delay" in the prosecution of the patent that cannot be attributed solely to the PTO will compel a decision adverse to the patentee. *See Lilly*, Pet. App. at 24a-25a, n.7.

Amici curiae urge this Court to grant the petition with respect to the first question presented, namely, whether the Court of Appeals erred in invalidating claim 7 of the '549 patent on grounds of nonstatutory double patenting.[2] *Amici* note Lilly's arguments that the Federal Circuit's invocation of double patenting analysis was improper from the outset. *Amici*'s focus in this brief, however, is on the fact that in addressing double patenting (whether or not it was proper to do so), the Federal Circuit applied a legal analysis that was inconsistent with its own settled precedent and that represents a significant shift in the law. The *Lilly* decision defines a virtually unattainable standard for developers of basic and improvement inventions to avoid a charge of double patenting when their patents have issued in reverse order. In its petition, Lilly addresses this issue with respect to the law of laches, Pet. at 21-23. *Amici* discuss it *infra* in terms of the "one-way" and "two-way" tests the Federal Circuit and its predecessor court have developed for assessing double patenting under this fact pattern.

The availability of patents for improvement inventions—*i.e.*, later-discovered inventions that improve upon an earlier basic innovation—is a crucial stimulus to innovation in any area of technology. It is especially important in the biotechnology and pharmaceutical industries, where both basic and improvement patents afford critical protection as the fruits of research are developed and

---

[2] *Amici* express no views regarding the second question presented in the petition, which asks whether the court below properly held that Lilly could not cure an infirmity based on double patenting by disclaiming the terminal portion of the term of the '549 patent after it had issued.

improved to bring new drugs, therapies, and other products to market.

I. The Law of Double Patenting.

"Double patenting" refers generally to the improper procurement of two patents for the same invention.[3] The doctrine, developed through case law with little direction from Congress, is rooted in the constitutional authority to secure for inventors exclusive rights in their discoveries "for limited Times," U.S. Const., art. I, § 8, and in the provision of the Patent Act that an inventor may obtain "a patent"—that is, a single patent—for an invention, 35 U.S.C. § 101. A summary of its origin and key rules is necessary to appreciate the impact of the decision below.

A. Evolution of the Law of Double Patenting.

Disputes over double patenting date back almost to the enactment of the first patent statute. In a case involving patents issued to one Jesse Reed in 1807 and 1810, for example, Justice Story (sitting as Circuit Justice) held:

> It cannot be, that a patentee can have in use at the same time two valid patents for the same invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century. . . . [T]he inventor can have but a single valid patent for his invention; and . . . the first he obtains, while it remains unrepealed, is an estoppel to any future patent for the same invention founded upon the general patent act.

Odiorne v. Amesbury Nail Factory, 18 F. Cas. 578, 578 (C.C. D. Mass. 1819).

---

[3] As discussed below, "same invention" is a term of art in double patenting law. It is used here in its nontechnical sense.

In 1894, this Court observed:

> It is settled . . . that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent; and the cases . . . come to this point, and to this point only: That a letter patent may be granted where the invention is clearly distinct from, and independent of, one previously patented.

Miller, 151 U.S. at 199. In that case, however, "every claim of the 1881 patent could have been properly included and made a part of the claims of the 1879 patent." *Id.* at 201. Accordingly, "[t]he matter sought to be covered by the second patent is inseparably involved in the matter embraced by the former patent; and this, under the authorities, renders the second patent void." *Id.* at 200.

A fact situation similar to that of the present litigation arose at least as early as *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315 (1865). Hayden had filed a first patent application in 1854 for an improvement in a cotton cleaning machine, described separately and in combination with other features. In 1857, Hayden filed what would today be considered a divisional application directed to the improvement alone, and a patent was granted on that application the same year. "For some cause, however, the commissioner had not acted on [the 1854] application down till June, 1857," *id.* at 316, and did not grant a patent until 1860. This Court held that "[t]he last [patent], not the first, is void," *id.* at 319, notwithstanding that "[i]t did not appear that Hayden was guilty of any laches, or was in any default in reference to the delay of the commissioner," *id.* at 316.

In a series of cases beginning in the early 1960s, the Court of Customs and Patent Appeals ("C.C.P.A."), and later the Federal Circuit, refined the analysis for comparing claims in two patents or applications to determine whether

they are patentably distinct. It drew a distinction between double patenting involving claims that are effectively identical in scope and content, on the one hand, and double patenting based on claims of divergent scope, on the other. *See In re Vogel*, 422 F.2d 438, 441-442 (C.C.P.A. 1970). It found a basis for the former, which it termed "same invention" double patenting, in 35 U.S.C. § 101, which it construed to proscribe the grant of more than one patent containing identical claims. *Id.*

For claims of differing scope, the C.C.P.A. determined that the proper analysis was *analogous to*, but distinct from, that employed to assess obviousness under 35 U.S.C. § 103; hence the term "obviousness-type double patenting." *Id.* In particular, the test looks to whether the differences between the *claims* (rather than between the prior art and the thing claimed) would have been obvious to one having ordinary skill in the art, structuring the inquiry in the manner instructed by *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), in the context of § 103. *See generally In re Vogel*, 422 F.2d at 441-442. A claim may also be found unpatentable or invalid on these grounds if, in analogy to 35 U.S.C. § 102, it is "anticipated" by—that is, if it is broader than—a patented claim. *See, e.g., In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993). Because the C.C.P.A. and Federal Circuit have found that this type of double patenting lacks an express statutory basis, it is also referred to as "nonstatutory" double patenting.[4]

---

[4] Because "obviousness-type" is somewhat confusing where double patenting is demonstrated without reference to an obviousness analysis, *i.e.*, where one claim "anticipates" another, this brief employs the term "nonstatutory" double patenting.

B. Terminal Disclaimers Equitably Resolve Double Patenting Problems.

Prior to the 1952 Patent Act, ch. 950, 66 Stat. 809 (1952), the unavoidable consequence of double patenting was the invalidity of the later-issued claims. In that Act, however, Congress provided a mechanism in the form of the "terminal disclaimer," 35 U.S.C. § 253, which proved useful to equitably resolve double patenting problems within the PTO. Through this device, a patent owner may disclaim the portion of the term of a second-issuing patent that extends beyond the term of a first-issuing patent, and thus cause the second patent to expire on the same date as the first.[5] Concerns about an "unjustified timewise extension" of exclusivity, condemned under double patenting jurisprudence, thus become moot. *In re van Ornum*, 686 F.2d 937, 943-44 (Fed. Cir. 1982); *see In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring).[6]

A valid terminal disclaimer requires the patent owner to retain ownership of the terminally disclaimed patent and the referenced patent. *See* 37 C.F.R. § 1.321(c)(3). This requirement protects the public from harassment in the form of lawsuits brought by multiple parties holding patents to inventions that are not patentably distinct. A terminal disclaimer renders the two patents legally inseparable, as though all of the claims had in fact been issued in a single

---

[5] Even under a patent term measured as 20 years from the earliest claimed filing date, 35 U.S.C. § 154(a)(2), related patents will not necessarily expire on the same date. Such patents need not arise from the same original application, and patent terms may be adjusted independently to compensate the applicant for administrative delays in examination, 35 U.S.C. § 154(b).

[6] The late Judge Rich, who suggested the use of a terminal disclaimer to "cure" double patenting in *Zickendraht*, was—not coincidentally—a principal architect of the 1952 Patent Act.

patent. It is thus the practice of the PTO to require a terminal disclaimer when the claims of a later application are not separately patentable over (*i.e.*, are anticipated by or obvious in view of) the claims of a prior issued patent. These issues are discussed in *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998), to which *amici* commend this Court's attention as a particularly lucid exposition of the law at issue in this case.

C. The Two-Way Test Allows Independent Patents for Basic and Improvement Inventions, Regardless of the Order in Which the Patents Issue.

The law governing double patenting, properly applied, ensures that separate patents having distinct terms will be granted when justified—that is, where the claims of the two patents define patentably distinct inventions, as elaborated in *In re Vogel*, 422 F.2d at 441-442, and its progeny. Thus where an improvement invention, such as a chemical species, is claimed after the grant of a patent on a related basic invention, such as a chemical genus,[7] the claim to the species will merit a distinct and separate patent term if the species is novel and nonobvious over the genus.[8] In the

---

[7] A chemical "genus" is a class of compounds sharing structural similarities, while a "species" is a single compound within the class defined by the genus. Many important pharmaceutical inventions involve discoveries of unique, therapeutically useful species within a previously known class of chemical compounds (the genus).

[8] A claim to a species is patentable (not obvious) over a description in the prior art of a genus that includes it unless the prior art provides some specific motivation to select the species. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). The converse, however, is not true: a prior art description of a species anticipates any later claim to a genus that

ordinary case, *i.e.*, where an improvement invention is distinct from an earlier, patented basic invention, no terminal disclaimer will be required.[9]

This analytical framework breaks down, however, when—for whatever reason—the examination of the basic patent is delayed, and the PTO issues the improvement patent first. In the example of a chemical genus and species, a claim to a species in a first-issuing, but later-filed, patent would then "anticipate" a claim to the genus in a later-issuing patent. *See, e.g., In re Goodman*, 11 F.3d at 1053.

To preserve the right of a patent applicant in this situation to secure *both* a patent on a basic invention and an independent patent for a later improvement invention meeting all of the requirements for patentability, the Federal Circuit established a "two-way" test, whereby the PTO or a reviewing court must determine that the claims of *each* patent are unpatentable over the claims of the other before a terminal disclaimer may be required. *In re Braat*, 937 F.2d 589, 592; *In re Berg*, 140 F.3d at 1432. In contrast, a "one-way" test asks simply whether the claims of the later-issuing patent are unpatentable over the claims of the first, without regard to the order in which the patents were filed.

---

includes it, rendering the generic claim unpatentable under § 102. *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960).

[9] A rule that automatically imposed a requirement for a terminal disclaimer in such circumstances would unfairly penalize the patent holder, denying a full patent term for a patentable improvement. The first panel decision in these proceedings, Pet. App. at 57a, *vacated en banc* Pet. App. at 37a-38a, did announce such a rule, prompting no fewer than six parties, including the present *amici*, to file briefs *amici curiae* urging the Court of Appeals to rehear the case *en banc*. The second panel decision does not suffer from the same infirmity.

D. The Two-Way Test Is Applied Infrequently But Is Critically Important When Invoked.

The two-way test preserves the right of the inventor of both basic and improvement inventions to enjoy a full term of patent rights for each of his two patentable inventions. It is particularly important in the biotechnology and pharmaceutical industries, where applications claiming a genus and a species often do not issue in the order in which they were filed.

Before *Lilly*, the jurisprudence of the Federal Circuit and C.C.P.A. held that access to the two-way test was to be based on an evaluation of which party—the PTO or the applicant—controlled the relative rates of prosecution of the two applications. Under that standard, the two-way test "is a narrow exception to the general rule of the one-way test." *In re Berg*, 140 F.3d at 1432. Access to the two-way test thus traditionally has been reserved for situations where the prosecution of the later-issuing patent is delayed in the PTO for reasons largely beyond the applicant's control—for example, where an appeal is not promptly decided or where an interference proceeding is conducted.

As Lilly discusses at length in its petition, the PTO *affirmatively determined* the patentability under §§ 102 and 103 of its claim to the later-filed improvement invention over its patent describing the basic invention. As a result, a double patenting analysis arguably should never have come into play in the Federal Circuit's decision. Moreover, had the Federal Circuit properly applied a two-way test, the '549 patent would not have been found invalid on the grounds cited in *Lilly*. The fact that the two patents issued with unlinked terms supports the notion that the PTO did not consider Lilly's prosecution of the later-issuing patent to be dilatory.

Quite apart from any impropriety of introducing the question of double patenting into this case, however, *amici*

wish to call the Court's attention to the Federal Circuit's *ensuing misapplication* of the law governing access to the two-way test. In its decision, the court below announced a new, blunt standard that prejudices the legitimate interests of patent owners who are not dilatory in prosecuting their applications before the PTO. Under the new rule, the court asks whether the PTO was "*solely* responsible" for any delay in prosecution, *Lilly*, Pet. App. at 24a-25a, n.7 (quoting *In re Berg*,[10] 140 F.3d at 1437; emphasis supplied by the *Lilly* court). The new standard essentially dictates that a one-way test will be imposed on "reverse-order" patent applicants in all but the most exceptional situations. The consequences of the new standard—effectively, the denial *a priori* of the full term of patent protection for some patentable inventions—are so powerful as to warrant this Court's review.

II. *Certiorari* Should Be Granted Because *Lilly* Conflicts with Federal Circuit Precedent Without Overruling It, Leading to Confusion in the Law.

One of the questions raised by the *Lilly* decision is how a patent applicant's conduct before the PTO should affect a double patenting analysis when the patents are issued in reverse order. The answer to this question determines whether a patent providing the full statutory term of exclusivity, *i.e.*, free of a terminal disclaimer, will be granted over a patent "for an improvement of a patentable character . . . where the invention is clearly distinct from, and independent of," the basic invention claimed in the later-issuing application, *Miller*, 151 U.S. at 199.

The trend in the Federal Circuit's decisions in the last decade has been toward more restricted, albeit considered, application of the two-way test in reverse-order nonstatutory

---

[10] The quoted phrase occurs in a discussion of a legal rationale that the *Berg* court did *not* apply on the facts before it.

double patenting situations. Nevertheless, the wooden rule announced in *Lilly* is incompatible with those decisions, as it unjustifiably constrains the analysis in a manner dangerous to patent policy and technological innovation.

In *In re Braat*, 937 F.2d at 593-594, the Federal Circuit formalized an approach for the treatment of claims in reverse-order situations. Reasoning that "an applicant . . . who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control," the court found that "it is not [the assignee's] fault that the combination claims in the ["improvement"] patent issued first." *Id.* at 593-94. On the facts of that case, it held that a two-way test should be applied.

In re Goodman, in contrast, applied a one-way test to generic claims in a continuing application having the same disclosure as its patented "parent," which claimed a species encompassed by the later-claimed genus. Finding that "PTO actions did not dictate the rate of prosecution" of the later application, the court held the broader claims unpatentable in the absence of a disclaimer. *Id*, 11 F.3d at 1053. Similarly, *In re Emert*, 124 F.3d 1458, (Fed. Cir. 1997), denied the applicant use of the two-way test because it had "orchestrated the rate of prosecution for the two applications." Having delayed a substantive response to the PTO for two years by taking extensions of time and filing continuation applications, the applicant was held "responsible for the delays in prosecution." *Id.*, 124 F.3d at 1461.

In *In re Berg* the applicant sought to test the independent patentability of claims to a genus and an included species by simultaneously filing separate, unrelated, but substantially identical applications. Finding the "control of prosecution rates" standard improper on the facts of that case, the court applied a one-way test "because

Berg could have filed the claims of its separate applications in a single application, and it simply chose to file two applications despite nearly identical disclosures." *Id.*, 140 F.3d at 1433.

Each of these decisions reflects a consideration of the patentee's behavior in light of the prosecution history *as a whole* to ascertain whether the application of the two-way test, and thus the absence of a terminal disclaimer, would result in an "unjustified timewise extension of the right to exclude granted by a patent," *In re Braat*, 937 F.2d at 594. This language resonates in equity. Taking due regard of the public interest, the Federal Circuit—prior to *Lilly*—has followed an essentially equitable approach, taking account of *all* of the relevant facts to determine the availability of the two-way test in its nonstatutory double patenting analysis.

The Federal Circuit's opinion in *Lilly* represents a significant departure from the approach of *Braat*, *Goodman*, *Emert*, and *Berg*. The only indication that the court even considered Lilly's actions before the PTO is found in a single footnote, where the panel concluded that "... the PTO was not solely responsible for the delay." *See Lilly*, Pet. App. at 24a-25a, n.7. The opinion did not otherwise consider the nature of the delay or whether Lilly's actions were objectively reasonable or appropriate.

The rule under *Lilly* is virtually automatic. In the face of *any* evidence of *any* delay arguably caused by the applicant, the two-way test will be denied. *Amici* contend that Federal Circuit precedent requires a more detailed and context-sensitive inquiry than that set forth in *Lilly*. Principles of equity and fairness warrant the award of a complete term of patent protection when the grant of a second patent is delayed for reasons beyond the exclusive control of the applicant. Retention of the *Lilly* standard, which grants full and independent terms only when the PTO is "*solely* responsible" for the delay, will unreasonably prejudice the ability of innovators to enjoy such protection,

and these conflicting precedents will create confusion in the law.

III. *Certiorari* Should Be Granted Because *Lilly* Significantly Affects Important Questions of Patent Policy, Threatening Great Harm to Technological Innovation.

Patent applicants often claim their inventions broadly at an early stage and then more narrowly as the inventions are refined and further developed, particularly as the commercial application of the technology becomes clear. Basic and improvement patents each promote innovation, and patents on each provide critical incentives for bringing a stream of new and improved products to market.

There are serious consequences for public policy in the *Lilly* court's rule. Unchecked, it will lead to an effectively *per se* rule in the PTO, imposing the one-way test on all patents that issue in reverse order and resulting in unjustified requirements for terminal disclaimers. Worse, it will lead to the inappropriate invalidation of claims in distinct patents that *each* fully meet the requirements for patentability. The significant harm to innovators that would flow from the broad application of the new rule strongly militates in favor of review by this Court of the decision below.

A. The *Lilly* Rule Will Discourage Innovation.

The wooden formula announced by the Federal Circuit will ensnare many patent applicants who have prosecuted their patents promptly and in good faith but have taken some action that can be characterized as contributing in some manner to a delay before the PTO. Regardless of the facts before the court in *Lilly*, its legal rule is cast in such absolute terms that it is hard to imagine when *any* reverse-order patentee would be entitled to the two-way analysis.

The new rule will render the two-way test inaccessible in all but the most unusual situations, leading to profound

consequences. Applicants will often have no choice but to file terminal disclaimers to obtain comprehensive protection for all of their inventions. Without disclaimers, their later-expiring patents will be at risk of being invalidated altogether. In the view of *amici*, this result would be unfortunate and undesirable as a matter of public policy.

The last years of the patent term frequently yield the greatest economic return on commercially successful inventions, notably for those in the biotechnology and pharmaceutical industries, and, as such, provide a potent incentive to innovation. The premature termination of patent rights by disclaimer will significantly diminish the value of patents on inventions that fit this profile and will limit the capacity of the patent system to stimulate research and the refinement of inventions.[11]

Even for inventions that are not commercial blockbusters, a rule that too frequently forces the submission of terminal disclaimers will be harmful to the commercialization of inventions. Disclaimers not only curtail patent terms, but also require continuing common ownership of the cited and disclaimed patents. *See In re van Ornum*, 686 F.2d at 944-945; 37 C.F.R. § 1.321(c)(3). Where there is more than one patentably distinct improvement invention—for example, different drugs developed from a class of compounds—terminal disclaimers involving the same basic patent will preclude the independent transfer of rights to the patents. Restrictions on

---

[11] Through enactment of the American Inventors Protection Act of 1999 ("AIPA"), Pub. L. 106-113, 113 Stat. 1536, the Congress demonstrated its commitment to principles of balance and fairness in adjusting the term of a patent. *See* AIPA § 4402, *codified at* 35 U.S.C. § 154(b), providing for an extension of term equal to the total of delays attributable to the PTO, less any delays attributable to the applicant, as compensation to the patentee for failure of the PTO to examine an application in a timely manner.

transferability tend to lower the value of patents and ultimately impede the commercialization of new products.

Together, these factors will discourage use of the patent system in favor of trade secret protection, particularly for early-stage inventions. That, in turn, will deprive the public of early access to information on significant technological advances, including through the publication of patent applications as provided by 35 U.S.C. § 122(b). It is critical that the rule to determine the availability of the two-way test be fair and reflect due consideration of all of the affected interests.

B. Rapidly Developing Fields of Technology Are Particularly Vulnerable.

Patent applicants in competitive and rapidly developing areas of technology, such as biotechnology and computer-aided drug design, are especially susceptible to having patents on basic and improvement inventions issue in reverse order. Inventors in these fields must file their applications as they make their discoveries or risk a loss of patent priority. Yet claims to early-stage inventions typically take longer to examine simply because they are broad, requiring more extensive searches and raising more patentability issues than focused claims to defined improvements. Compounding the problem, the law and the PTO's administrative resources often fail to keep pace with the changing nature of inventions in these areas, delaying the examination of pathbreaking basic inventions further. Reverse-order double patenting problems are thus more likely to occur in the very fields where patent protection is most critical to securing a competitive advantage.

Emerging companies in new fields are often in a poor position to contest a rejection by the PTO based on double patenting. Many pharmaceutical and biotechnology innovators have no assets other than their *potential* patent rights. Many smaller companies, faced with double

patenting rejections, will elect to comply with requirements for terminal disclaimers to gain allowance of their patents, rather than invest time and scarce resources in an appeal. This is all the more likely where the controlling legal rule is so mechanical in its operation, and so easily triggered, as to disallow *a priori* almost any rebuttal evidence.

Because there is no statutory provision to withdraw a terminal disclaimer, the consequences of the *Lilly* rule are especially harsh. Once a disclaimer under 35 U.S.C. § 253 has been executed, the disclaimed term is irretrievably forfeited. Applicants have no option to provisionally disclaim part of the patent term pending resolution of their legal arguments before the Federal Circuit.

C. Patent Applicants Should Not Automatically Forfeit Rights for Any and All Prosecution Delays.

The *Lilly* rule holds that a delay that can be attributed *in any manner* to the applicant will act as a bar to use of the two-way test. Yet there are many situations where actions that arguably delay the grant of the patent are entirely legitimate practices endorsed by statute and regulation. For example, an applicant may take an extension of time to submit a response to a complicated rejection, or file a continuing application to further prosecution rather than appeal. Only on review of the *complete* prosecution history will it be clear whether the applicant's actions in their entirety constitute a deliberate pattern of delay.

An automatic result, based on evidence divorced from the context of the entire prosecution history, is not true to the equitable roots of double patenting jurisprudence. Neither is it true to this Court's observation that "[i]t is settled . . . that an inventor may make a new improvement on his own invention of a patentable character, for which he may obtain a separate patent." *Miller*, 151 U.S. at 199.

Amici believe that it is proper to divest a dilatory patent applicant of the protections of the two-way test. *De facto* elimination of the two-way test itself, however, will punish patent owners severely for any action during prosecution that can be characterized as even contributing to a delay. Basic fairness mandates that the legal rule for denying the two-way test invoke more than a cursory review of the prosecution history for which the applicant is to be held accountable.

D. Action By This Court Is Necessary To Restore a Proper Balance in the Law.

The effect of the *Lilly* decision will be felt most acutely by patent applicants. The PTO will undoubtedly provide guidance to its examiners concerning the application of *Lilly*. Even if the guidance urges restraint, however, *amici* fear that many examiners, already overburdened by the PTO's enormous and ever-increasing caseload, will gravitate toward the stark simplicity of a rule that requires a one-way test upon the identification of any minor "delay," whatever the intrinsic merits of the rule. It is simply human nature to resort to an expedient solution when it is available.

The current fractious state of the law prejudices the legitimate interests of patent applicants, litigants, research-based industries, and the public. This Court's guidance is now required to reconcile conflicting Federal Circuit precedents and to preserve the incentives for innovative improvements that the Court has recognized for more than a century.

CONCLUSION

For the foregoing reasons, *amici curiae* BIO and PhRMA respectfully request that this Court grant the petition for a writ of *certiorari*.

Respectfully submitted,

Of counsel:
Stephan E. Lawton
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Matthew B. Van Hook
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA

Jeffrey P. Kushan,
Counsel of Record
David L. Fitzgerald
Marinn F. Carlson
POWELL, GOLDSTEIN, FRAZER & MURPHY LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
(202) 347-0066

December 13, 2001